

REMARKS

In the Office Action dated September 24, 2007, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1-7 and 18-21, in so far as they are drawn to a method for diagnosing a nervous system disorder in a subject using an antibody as a probe.
- II. Claims 1-7 and 18-21, in so far as they are drawn to a method for diagnosing a nervous system disorder in a subject using a nucleic acid molecule as a probe.
- III. Claims 8-9, drawn to a method for identifying a compound useful for modulating the activity of an aPKC.
- IV. Claims 12, 14-16 and 18-21 in so far as they are drawn to a method for treating a nervous system disorder in a subject by means of gene therapy.
- V. Claims 22-23, drawn to an antibody that binds to an isoform of an aPKC molecule.
- VI. Claim 24, drawn to an antibody that binds to an isoform of an aPKC molecule.
- VII. Claims 25-30, drawn to a method for constructing an animal model of neurological dysfunction.
- VIII. Claims 31-34, in so far as they are drawn to a method for screening SEQ ID NO: 6 for a mutation or polymorphism in the sequence of the aPKC genes.
- IX. Claims 31-34, in so far as they are drawn to a method for screening SEQ ID NO: 7 for a mutation or polymorphism in the sequence of the aPKC genes.
- X. Claims 35-37, drawn to a method for diagnosing cancer.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group V, claims 22-23 drawn to an antibody that binds to an isoform of an aPKC molecule. However, pursuant

to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

In the first instance, Applicants observe that as admitted by the Examiner, the present application is a U.S. national stage application submitted under 35 U.S.C. § 371. The Examiner alleges that the present application lacks unity of invention. However, the Examiner's restriction requirement appears to apply both the unity of invention practice under PCT Rule 13 and the restriction practice in the U.S. For example, the Examiner alleges that the restriction is necessary because the listed groups are "independent or distinct." The Examiner alleges that a serious search and examination burden would occur for the reasons including that the listed groups have acquired "a separate status in the art in view of their different classification." See Item 3 on page 4 of the Restriction Requirement. In this regard, Applicants respectfully direct the Examiner's attention to MPEP §1893.03(d), which states that "Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage applications submitted under 35 U.S.C. 371" (emphasis added). Notably, when alleging the listed groups as independent or distinct, or having acquired separate status with different classification, the Examiner has failed to state a single classification in any listed group in the first place.

For the reasons stated above, Applicants will address the present restriction requirement under PCT Rule 13 only. Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features"

shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

At the outset, Applicants observe that the Examiner fails to provide any specific reason to allege that Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1. The Examiner merely states in general, without a reason, that the listed groups do not conform to one of the acceptable combinations of categories pursuant to 37 C.F.R. § 1.475(b).

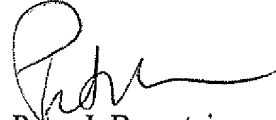
Applicants respectfully submit that the present application is predicated in part on the recognition that an increase or a decrease in aPKC activity can lead to the development of pathological changes in cells, leading to nervous system dysfunction and cancer. The present invention recognizes that alteration in aPKC signaling contributes to the pathogenesis of nervous system disorders, such as Alzheimer Disease (AD). The unique recognition of the present application provides the basis for employing aPKC as a novel target for rational drug design useful for modulating aPKC activity for the purpose of treating nervous system disorders and providing methods for diagnosis of nervous system disorders. It is respectfully submitted that all claims presented in the present application share the technical feature of modulating aPKC activity in a subject. It is submitted that the present claims, when considered as a whole, define a contribution over the prior art, and should be examined in the same application. Applicants respectfully submit that Groups I-X are different aspects of a single invention.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined ten groups, one from the other, as presented by the Examiner.

Accordingly, it is respectfully submitted that Claims 1-9, 12, 14-16 and 18-37 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner

reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the pending claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter I. Bernstein", written over a horizontal line.

Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 Garden City Plaza - Ste. 300
Garden City, New York 11530
(516) 742-4343
ZY:ab